

**FEE**

**DATE OUT: 15/MAR/2006**

**FEE: PRODUCT CHEMISTRY REVIEW OF: AN End-Use Product [X]**

**DP BARCODE #:D323063 RECEIVED DATE 28/OCT/2005 FILE SYMBOL: 39967-LG**

**PRODUCT: KBR 3023 All-Family Insect Repellent MRIDs 466620-01 ACTION CODE: R33**

**COMPANY NAME: Lanxess Corporation NON-FOOD USE [X]**

**PPC NUMBER OF THE TGAI IN THE PRODUCT: 070705 DECISION NO.: :361212**

**FROM:** Sami Malak, Chemist *S. Malak*  
Technical Review Branch/RD (7505C)

*SRW*  
*03-16-06*

**TO:** 10 Richard Gebken/Joseph Tavano  
Insecticide-Rodenticide Branch/RD (7505C)

**INTRODUCTION:**

In a letter dated 03/OCT2005 the applicant requested registration of subject product. In support of this application, the applicant included product chemistry data, a basic CSF dated 23/AUG/2005, a proposed label EPA received on 14/OCT/2005, Certificate With Respect to Citation of Data, and Data Matrix.

**FINDINGS:**

- 1a. The subject product was produced by a non-integrated formulation system, meaning that the active ingredient in the product is registered. The product contains 20% Picaridin, Reg. No. 39967-48.
- 1b. The subject product, an insecticide, is intended for use as an insect repellent.
- 2a. The applicant should be advised to submit the results of product's storage stability and corrosion characteristics, two product chemistry data requirements of GRNS 830.6317 & 830.6320, respectively.
- 2b. With the exception of the data gaps in Finding 2(a) above, the submitted product chemistry data is adequate and support registration of subject product.
3. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the technical source, Picaridin, Reg. No. 39967-48. No method was included with this submission.
4. The label claim nominal concentration of 20% Picaridin, is consistent with that in the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.78.

5. The proposed basic CSF dated 23/AUG/2005 was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations intended for non-food uses.

### **CONCLUSIONS:**

After resolving Findings 2(a), the TRB will have no objections for registration of subject product. The proposed basic CSF dated 23/AUG/2005 and label, EPA received on 14/OCT/2005 are acceptable as per Findings 4 & 5 above.

### **REVIEW OF PRODUCT CHEMISTRY DATA:**

1. A statement of data confidentiality dated 23/AUG/2005 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data was removed to Confidential Appendix A.
2. A GLP statement dated 02/OCT/2005 was included with this submission to the effect that none of the submitted studies were conducted in compliance with the GLP requirements of 40CFR§160.

### **Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)**

#### **830-1550 Product Identity and Composition**

This product contains one technical grade of an active ingredient currently, plus intentionally added inert ingredients cleared for non-food uses (refer to product's basic CSF dated 23/AUG/2005).

#### **830-1600 Description of Materials Used to Produce the Product:**

Refer to Confidential appendix A.

#### **830-1650 Description of Formulation Process:**

Refer to Confidential appendix A.

#### **830-1670 Discussion of Formation of Impurities:**

Refer to Confidential appendix A.

#### **830-1700 Preliminary Analysis:**

Refer to Confidential appendix A.

#### **830-1750 Certified Limits:**

Refer to Confidential appendix A.

### 830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the technical source, Picaridin, Reg. No. 39967-48. No method was included with this submission.

An analytical method was included in connection with Reg. No. 121-OT, MRID #466680-03. The method, reviewed by this reviewer, can be used for enforcement. The method is entitled "Gas Chromatography Determination of KRB 3023 and Sunscreen Active Ingredient Content in Certain Repellent Formulations." KRB 3023 is the trade name for Picaridin.

The method uses FID and dibutyl phthalate internal standard for the determination of the active ingredient and three sunscreens in the product. In this method, samples are extracted using acetone then mixed with an internal standard and aliquots are injected into the GC. The retention time for the PAI was reported at 5.5 minutes.

Method validation data regarding recovery, accuracy, precision, and linearity are adequate. Sample calculations and chromatograms are included with this submission.

### Identity, Composition, Formulation, and Analysis, Subgroup A, Series 830.1550 to 830.1800 (40 CFR 158.155 to 158.180)

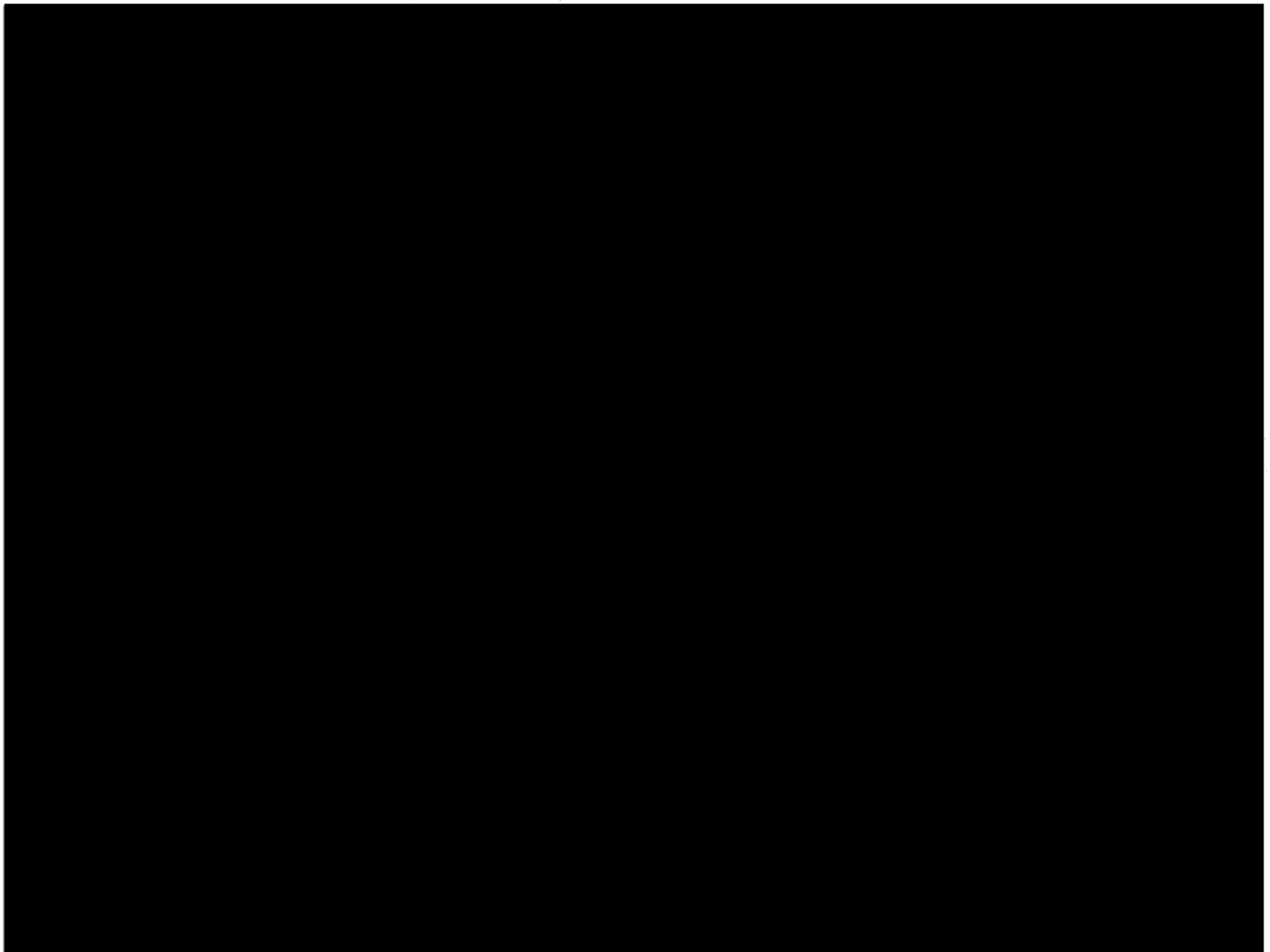
Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	MRID No.
.1550 Product identity and composition	Y	466620-01
.1600 Description of materials used to produce the product	Y	466620-01
.1620 Description of production process	NA	
.1650 Description of formulation process	Y	466620-01
.1670 Discussion of formation of impurities	Y	466620-01
.1700 Preliminary analysis	NA	
.1750 Certified limits	Y	466620-01
.1800 Enforcement analytical method	Y	466620-01

Explanations: Y = The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.

**Physical and Chemical Properties, Subgroup B, Series 830.6302 to -830.7300 (40 CFR 158.190)**

Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	Value or Qualitative Description	MRID No.
.6302 Color	Y	Colorless.	466620-01
.6303 Physical state	Y	Liquid.	466620-01
.6304 Odor	NA	As per PR Notice 92-5.	466620-01
.6314 Oxidation/reduction: Chemical incompatibility	NA	No oxidizing or reducing potential exist.	466620-01
.6315 Flammability/flame extension	Y	Flash point 28°C (82.4°)	466620-01
.6316 Explodability	NA	No impact explosive characteristics are expected on the basic of the chemical nature of the formulation ingredients.	466620-01
.6317 Storage stability	G		
.6319 Miscibility	NA	Not intended for dilution with petroleum solvents.	466620-01
.6320 Corrosion characteristics	G		
.6321 Dielectric breakdown voltage	NA	Formulation is not intended for use around electrical equipment.	466620-01
7000 pH	Y	7-9	466620-01
.7100 Viscosity	Y	7-9 m Pas @ 20°C	466620-01
7300 Density/relative density/bulk density	Y	0.977 – 0.987	466620-01
Explanations: Y =The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.			

**Confidential Appendix A**



cc:S. Malak and Central File (Reg. No.39967-LG).  
7505C:RD:TRB:CM-2:268:s.m.:15/MAR/2006:703-308-9365:<39967-LG>.